

The Center for Science in the Public Interest (a credible nonprofit based in Washington, DC).
Letter to Georgetown Univ. (about the Gots/Georgetown affiliation and upcoming conference).

May 6, 2002

John J. DeGioia, Ph.D.
President
Georgetown University
37th and O Sts. N.W.
Washington, DC 20057

Dear Jack,

I am writing to you about a matter of urgency and concern. I write as a member of the Georgetown community, an ethicist, a former member of the Georgetown University Medical Center CME Review & Development Committee, and as an advocate for responsible science.

A course called "Mold Medicine and Mold Science: Its (sic) Practical Applications for Patient Care, Remediation and Claims," sponsored by the International Center for Toxicology and Medicine (ICTM) and the G.U. Department of Pharmacology is scheduled to be held at the G.U. Conference Center on May 13-14, 2002. The course was originally granted 10 hours of AMA Category 1 CME credit by the Georgetown University Hospital CME Review & Development Committee. Numerous violations of the ACGME application requirements were brought to the attention of the CME Committee by Albert Donnay, the President of MCS Referral and Resources (a patient advocacy organization devoted to multiple chemical sensitivity disorders) and the Committee subsequently withdrew the credits for the course. (See enclosed correspondence).

Having withdrawn the credits, the CME Committee and the Office of Post Graduate Education have apparently divested themselves of responsibility for the course. (See March 24, 2002 letter from Shelly Monks to Albert Donnay)

Albert Donnay contacted me about this matter because I direct the Integrity in Science Project at the Center for Science in the Public Interest. The focus of the Project is on conflicts of interest and the role that corporate funding and other corporate interests play in scientific research, oversight, reporting and science-based policy. Among other things, we sponsor a database www.integrityinscience.com that discloses scientists' and nonprofits' ties to industry.

As I read the correspondence surrounding this matter, I am troubled by the ill-advised partnership between Ronald Gots, MD, founder and Principal of ICTM and members of the Georgetown Department of Pharmacology, Sorrell Schwartz, PhD and Philip Witorsch, MD, FACP, FCCP, both of whom are not only Principal's of ICTM, but who also apparently (according to Gwen Funderburk) receive research funding from ICTM. The conflicts of interests involved in such an arrangement are glaring. Add to this the fact that Dr. Schwartz teaches the required research ethics course at the Medical Center and you have a serious threat to the credibility and reputation of the Medical Center and the University.

(See <http://www.georgetown.edu/departments/pharmacology/ethics.html> accessed 5/1/02)

I am troubled by the imprudence of the Department of Pharmacology in sponsoring a course that:

1. Has no clear connection to patient care but rather is focused on strategies for defense litigation in mold cases brought by patients.

2. Is in clear violation of the ACGME requirements (that courses be developed independently by individuals who are not associated with the course sponsor)
3. Is in violation of the longstanding practice of the G.U. CME Review & Development Committee to reject sole-sponsor applications for conferences that clearly serve the proprietary interests of the sponsor.

I am also troubled by the imprudence of the Department of Pharmacology in granting Dr. Gots' faculty status, which according to Dr. Gots' 2001 *curriculum vitae* includes "Lecturer in Pharmacology" and "Adjunct Associate Professor." As you will see from the accompanying materials, Dr. Gots' company, Medical Claims Review Services (MCRS) was the subject of a 1999 *Washington Post* article and *Dateline* expose on insurance fraud. This company still operates out of the same offices as ICTM.

I urge you to take a number of steps:

First and immediately, to withdraw all Georgetown sponsorship of this course. This will include Pharmacology Department sponsorship as well as invoking any clause in the University or Hospital's contract with the Georgetown Conference Center regarding programs or courses inappropriate to the University's mission.

Second, to investigate the conflict of interest in research support apparently provided to members of the Department of Pharmacology by ICTM to determine (a) members do receive such support; (b) if this support has biased the research findings; (c) if this research support was the basis of a quid pro quo arrangement granting faculty status to Dr. Gots; (d) if this support inappropriately influence the Pharmacology Department's and CME Committee's oversight of course development and the CME application process.

Third, to determine if the Pharmacology Department faculty affiliation with ICTM is consistent with regulations governing outside faculty work and conflicts of interest.

Fourth, to consider, on the basis of these investigations, removing Sorrell Schwartz as the faculty member for the required research ethics course.

Fifth, to request a thorough review of the Georgetown University Hospital CME Review & Development Committee process concerning this course to determine why its oversight failed. It is my understanding that the CME office has traditionally run a deficit and this has been justified by the office's contribution to the internal educational mission of the University and by the Medical Center's outreach to community physicians. I also understand that CME is now under Hospital management and has, for the first time ever, been given income projections for the year. The potential for conflict of interest in the context of continuing medical education is great. This is why ACGME has established regulations to create firewalls and prevent proprietary interests from unduly influencing course material. If CME offices are pressured to bring in income, they can easily be tempted to cut corners, thus jeopardizing the content of course offerings and the integrity and credibility of the sponsoring institution.

I urge you to take action on these matters. Please feel free to contact me to discuss this further.

Sincerely,

Virginia A. Sharpe, Ph.D.
Director, Integrity in Science
202-777-8331
cc. Dr. M. Joy Drass, President, Georgetown University Hospital